

WILMERHALE

February 1, 2016

John J. Regan

Honorable Alison J. Nathan
United States District Judge
Thurgood Marshall United States Courthouse
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Re: *Braintree Laboratories, Inc. v. Breckenridge Pharmaceutical, Inc.*, Civil Action No. 12-cv-6851-AJN [rel. 14-cv-8147-AJN]

Dear Judge Nathan:

This firm represents Plaintiff Braintree Laboratories, Inc. (“Braintree”) in the above-referenced action. I write to clarify and supplement certain statements made in the letter submitted by counsel for Defendant Breckenridge Pharmaceutical, Inc. (“Breckenridge”) on January 27, 2016. Dkt. No. 102, 103.

Breckenridge states that briefing in the pending appeal *Braintree Laboratories, Inc. v. Novel Laboratories, Inc.*, No. 15-1700 (Fed. Cir.) (the “Novel appeal”) was “delayed.” Dkt. No. 103. Briefing in the Novel appeal proceeded in the normal course. The parties received extensions typically granted by the Federal Circuit. *See* Fed. Cir. Rule 26(b), 27(h), Practice Notes; Fed. Cir. Guide for Motions Practice § 4, <http://www.cafc.uscourts.gov/guides/guide-for-motions-practice> (“An unopposed motion for an extension of time, up to 60 days for each principal brief and up to 30 days for other deadlines, can be granted promptly by the clerk of court.”). Briefing in the Novel appeal is now complete. We anticipate that the case will be scheduled for oral argument before the Federal Circuit in April, May or June.

Breckenridge implies that the Court’s “action on Breckenridge’s Motion” in this matter will allow Breckenridge to “move forward toward providing the public with a generic product.” Dkt. No. 103. But Breckenridge was not the first generic company to file an Abbreviated New Drug Application (“ANDA”) on Braintree’s SUPREP colonoscopy prep. A number of other companies, including at least Novel Laboratories, Inc., Paddock Laboratories, Inc., and Taro Pharmaceutical Industries, Ltd., have filed ANDAs on SUPREP. Another company, Gator Pharmaceuticals, Inc., has filed an NDA application under 21 U.S.C. § 355(b), directed to SUPREP and U.S. Patent Number 6,946,149, the patent at issue in this action. All of these parties have been the subject of federal court patent infringement actions brought by Braintree. The pending Taro and Gator cases have been administratively stayed, subject to periodic updates, while awaiting resolution of the Novel appeal to the Federal Circuit. The update for the Taro case is due to be filed with this Court in June, 2016.

In addition, Braintree believes that Novel Laboratories, Inc. was the first ANDA filer. Under the Hatch-Waxman Act, first filers may be entitled to 180-day market exclusivity before any subsequent ANDA filers are allowed to enter the market. *See* 21 U.S.C. § 355(j)(5)(B)(iv) (ANDA of subsequent filer “shall be made effective on the date that is 180 days after the date of the first commercial marketing of the drug...by any first applicant”).

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We appreciate the Court's consideration.

Respectfully submitted,

/s/ John J. Regan

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Cc: All counsel of record (via email)